Procedure Title: Preparation and Approval of Institutional Review Board Meeting Minutes

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	1/22/2021	**Executive Lead:**	Chief Research Officer
Effective:		**Revision History:**	.00 – 04-13-2021; .01 / 3/27/2023
Approved by:	Institutional Review Board		
Procedure Number:	152.01		
Key Words:	Quorum		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:
This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding the preparation and approval of PNWU Institutional Review Board (IRB) Meeting Minutes.

This SOP must be used as a guide in parallel with OSA Policy 1.0. SOPs are not intended to supersede existing institutional policies, or local, state, and federal laws and regulations.

General Information:
The federal regulations for the protection of human subjects require the Institutional Review Board (IRB) to prepare and maintain adequate documentation of IRB actions, including meeting minutes. IRB meeting minutes must contain sufficient detail to show the review of proposed research activity and any vote taken by the IRB related to proposed research activity.

Complete meeting minutes enable the reader to determine how and with what justification the IRB arrived at its decisions. The minutes must also provide the IRB with sufficient detail to help reconstruct its discussions and decisions, at a later date/time, if necessary. Meeting minutes and the proceedings, to the extent possible, are confidential.

Responsible Parties:

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants;
- Impartiality when reviewing human subjects research;
- Remaining immune from pressure by the institution's administration, the investigators whose protocol are brought before it, or other professional and non-professional sources

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting the investigator in the development of research protocols and the source documents required for the conduct of research;
- Overseeing and providing an adequate amount of support to the IRB to enable compliance with federal regulations;
- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community.

The IRB Administrator or designee is responsible for:

- Attending IRB meetings and recording the IRB meeting minutes in sufficient details to meet the federal regulations;
- Distribution of the IRB meeting minutes for review by members of the IRB

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Quorum

Procedures:

Meeting Attendance and Quorum:

1. The IRB administrator or designee will take attendance prior to beginning each meeting.
2. The meeting minutes will include which attendees are alternate members and the name of the primary member for which they are substituting.
3. If consultants are invited to the meeting, the name of the consultant must be included in the meeting.
4. The meeting minutes must include which members, if any, participated in the convened meeting via alternative mechanism, such as video conference or telephone.
5. The meeting will begin after a quorum is confirmed.
    a. Quorum is achieved when half-plus-one of the members attend or in the case of an odd number of members, then a majority of the members must attend. (e.g., 11 members, half of which is 5.5, so a majority would be 6 members).
    b. The attendees must include one scientific member, one nonscientific and one nonaffiliated member.
6. A quorum must be maintained throughout the meeting. If a quorum is lost, the IRB may not deliberate or vote on study actions until a quorum is restored.
7. Individuals such as, but not limited to, students may request to attend the meeting as observers. Requests to attend the meetings must be made one week prior to a scheduled meeting. The IRB chair may grant permission for attendance. Observers do not receive a copy of the application or IRB materials and will be asked verbally to agree to keep meeting details confidential.
8. Meeting attendance will be entered into the electronic IRB system after the meeting.

Minutes Preparation:

1. The IRB Administrator or designee will take detailed notes to document the IRB proceedings, discussions, and determinations.
2. The IRB meetings are recorded (video and audio) to assist with accuracy of the meeting minutes. The recordings are deleted as soon as the meeting minutes have been transcribed into the electronic IRB system.
3. The meeting minutes of the convened committee will include the following general information:
    a. Meeting location and/or platform (e.g., Zoom) and the time at which the meeting began and adjourned.

b. Attendance – The names of every member present and their affiliation (scientific, nonscientific, unaffiliated, prisoner representative) and if other than a primary member (e.g., alternate). Additionally, any guests, consultants, nonvoting members, and IRB office staff will also be listed. Documentation will be made regarding whether or not quorum is achieved.
c. Whether an alternate member is voting and for whom.
d. A summary of exempt and expedited reviews and approvals that have taken place outside of a convened meeting (including study number and study title).
e. Actions taken by the IRB.
f. When a member leaves the room or meeting OR when a member enters the meeting or returns to the meeting, as well as the time when members of the IRB arrive after the meeting has begun.
g. When a member is attending the meeting via telephone or teleconference, and
h. Any new conflicts of interest disclosed.

4. The meeting minutes on the review of a study protocol undergoing full board review will include the following additional information:
    a. The protocol number and name of the studies being reviewed.
    b. The name of IRB members who recuse themselves from the meeting due to conflict of interest during discussion and vote on a study.
    c. The time and name(s) of researchers entering the convened meeting to answer IRB questions.
    d. The time that the researcher(s) exit the meeting prior to final discussion and vote on the researcher's study protocol.
    e. A vote on the actions being taken as well as documentation of the number of votes (for, against, and abstain).
    f. A written summary of any discussion and/or controverted issues and their resolutions.
    g. The basis for requiring changes, if any, to the research.
    h. For any protocol approved at the meeting, documentation that the criteria for approval have been met.
    i. If the IRB disapproves a study protocol, the IRB staff will document the reason(s) for the disapproval.
    j. Any additional special or specific findings at convened meetings will be documented. These may include specific requirements or procedures when waiving the requirement for obtaining a signed consent form, approving research with a vulnerable population (e.g., prisoners, children, pregnant women, human fetuses, or neonates), determining that emergency research meets the criteria found in the regulations, or if an FDA regulated medical device poses a significant risk (SR) or nonsignificant risk (NSR) to research subjects when the FDA has not already made a risk determination.
    k. If the IRB takes action to suspend or terminate IRB approval during a convened meeting, a statement of reasons for the IRB's actions must be documented in the meeting minutes. The minutes should also include any required follow-up actions.
    l. If the IRB takes action to suspend or terminate IRB approval of a study outside of a convened meeting (e.g., as determined by the IRB chair or institutional official for safety reasons), the actions will be reported at the next convened IRB meeting. Discussions will be summarized in the meeting minutes.

Distribution of the Minutes:

1. A copy of the draft meeting minutes for the previously held IRB meeting will be included in the meeting packet and distributed one week prior to the scheduled meeting. The full meeting packet is also posted in the electronic IRB system one week prior to a scheduled meeting.

2. Final meeting minutes are posted in the electronic IRB system.

Approval of Meeting Minutes:

1. A copy of the meeting minutes for the previously held IRB meeting will be included in the monthly meeting packet for review.
2. At the convened meeting, the committee will be asked if there are any revisions. If no revisions are required, the chair will call for a motion to approve the meeting minutes.
3. Committee members will be asked to vote for, against, or abstain from voting.
4. Approval of the meeting minutes does not require maintaining quorum. The meeting minutes will be approved when a majority of the members present vote to approve.

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 46, 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm
4. U.S. Food and Drug Administration Guidance, Minutes of Institutional Review Board (IRB) Meetings, September 2017 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/minutes-institutional-review-board-irb-meetings
5. FDA Investigational Device Exemptions (21 cfr 812)
6. Robert's Rules of Order Revised in Brief, c2020.

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 04-26-2021	C. Case	Original SOP
.01 / 4-4-2023	C. Case	Punctuation corrections; revised #2 under distribution of meeting minutes – deleted the part of the sentence stating that meeting minutes will be posted in SharePoint. Meeting minutes are now posted in the new electronic IRB system.

Appendices: